

K060950

MAY 18 2006

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**SUMMARY OF SAFETY AND EFFECTIVENESS**

**MATERIALISE SIMPLANT SYSTEM**

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**PROPRIETARY NAME:**

3Matic

**COMMON NAME:**

Software for computer assisted design and manufacturing of medical and dental prostheses

**CLASSIFICATION NAME:**

Picture Archiving and Communications System

**DEVICE CLASSIFICATION:**

21 CFR 892.2050.

**REGULATORY CLASS:**

Class II

**CLASSIFICATION PRODUCT CODE:**

LLZ

**SUBSEQUENT PRODUCT CODES:**

NOF

**SUBMITTER'S NAME AND ADDRESS:**

MATERIALISE N.V.  
Technologielaan 15  
B-3001 LEUVEN, BELGIUM

**ESTABLISHMENT REGISTRATION NO:**

3003998208

**CONTACT PERSON:**

Carl Van Lierde, Materialise N.V.  
Quality Manager

**SUMMARY PREPARATION DATE:**

March 21, 2006

**PREDICATE DEVICE**

**3Matic** is claimed to be substantially equivalent in material, design, and function to the SimPlant System, which was cleared by FDA under 510(k) K033849 on May 25, 2004.

**3Matic** is claimed to be substantially equivalent in material, design, and function to the Etkon ES-1 product from Etkon, which was listed with FDA on January 4, 2005.

### **INDICATIONS FOR USE**

Materialise's **3Matic** is intended for use as software for computer assisted design and manufacturing of medical exo- and endo-prostheses, patient specific medical and dental/orthodontic accessories and dental restorations.

### **STERILIZATION**

The **3Matic** is provided non-sterile.

### **SUBSTANTIAL EQUIVALENCE**

The **3Matic** is considered to be substantially equivalent to the SimPlant System and Etkon ES-1.

### **CONCLUSION**

The **3Matic** is considered to be substantially equivalent in design, material and function to the SimPlant System and Etkon ES-1.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
9200 Corporate Blvd.  
Rockville MD 20850

Mr. Carl Van Lierde  
Quality Manager  
Materialise NV  
Medical Division  
Technologielaan 12, Leuven 3001  
BELGIUM

MAY 18 2006

Re: K060950  
Trade/Device Name: 3Matic  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture archiving and communications system  
Regulatory Class: II  
Product Code: LLZ  
Dated: March 27, 2006  
Received: April 6, 2006

Dear Mr. Van Lierde:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.



*Protecting and Promoting Public Health*

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

|                 |                                  |              |
|-----------------|----------------------------------|--------------|
| 21 CFR 876.xxxx | (Gastroenterology/Renal/Urology) | 240-276-0115 |
| 21 CFR 884.xxxx | (Obstetrics/Gynecology)          | 240-276-0115 |
| 21 CFR 892.xxxx | (Radiology)                      | 240-276-0120 |
| Other           |                                  | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

K 06 0950

## Indications for Use

510(k) Number (if known):

Device Name: 3Matic

Indications For Use:

Materialise's **3Matic** is intended for use as software for computer assisted design and manufacturing of medical exo- and endo-prostheses, patient specific medical and dental/orthodontic accessories and dental restorations.

Prescription Use ☒  
(Part 21 CFR 801 Subpart D)

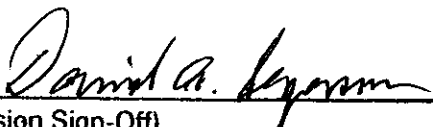
AND/OR

Over-The-Counter Use ☐  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K060950